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First Named Inventor	John D. Baxter	
Group Art Unit	1631	
Examiner Name	Carolyn L. Smith	
Attorney Docket Number	407J-981114US	

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Appl. No.

10/827,121

Confirmation No. 1501

Applicant

John D. Baxter, et al.

Filed

April 16, 2004

TC/A.U.

1631

Examiner

Carolyn L. Smith

Docket No.

407J-981114US

Customer No.:

22798

Client Ref No.:

SF96A-026-7

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

In response to the Restriction Requirement mailed August 9, 2006, Applicants respectfully request reconsideration of the above-identified application in view of the following remarks.

Claims 61 to 82 are currently pending. Applicants provisionally elect to prosecute, Group I claims 61-82 wherein species of claims 66, 76, 78, 80 and 82 drawn to models of a hormone receptor based on structural information data from Appendix 3, with traverse.

Applicants note that restriction between species within a claim is not proper based on 35 U.S.C. §121. Should the Office be persuaded that the proper administrative function is election of species according to 37 CFR 1.146, Applicants would elect to the species of Appendix 3 for current consideration.

The Restriction

In the Office Action, the claims for current consideration have been restricted to one of the following groups under 35 U.S.C. §121:

Group I: claims 66, 76, 78, 80 and 82, drawn to data from Appendix 3, class 703/11. Group II: claims 66, 76, 78, 80 and 82, drawn to data from Appendix 4, class 703/11. Group III: claims 66, 76, 78, 80 and 82, drawn to data from Appendix 5, class 703/11. Group IV: claims 66, 76, 78, 80 and 82, drawn to data from Appendix 6, class 703/11. Group V: claims 66, 76, 78, 80 and 82, drawn to data from Appendix 7, class 703/11. Group VI: claims 66, 76, 78, 80 and 82, drawn to data from Appendix 8, class 703/11.

Applicants note that the Group listing provided in the Action provides five claims each for consideration in six Groups, all in the same class and subclass of art. Applicants note that currently pending claims 61-65, 67-75, 77, 79 and 81 are not members of any Group provided in the Action. Applicants note that 35 U.S.C. §121 enables the Office to restrict claims of an application into groups containing different inventions. Applicants note that applicants have the right to have each claim examined on the merits as presented, and that restriction of single claims for division into multiple applications would generally infringe on this right (see, *In re Weber*, 198 USPQ 328 (CCPA 1978)). Applicants note that, according to MPEP 804, the Office can require an inventor to elect species within a claim for current consideration according to 37 CFR 1.146, but this does not enable the Office to dismember the claims with a Restriction Requirement based on 35 U.S.C. §121.

Applicants propose the following alternate Restriction Grouping:

Group I: claims 61-82, drawn methods of modeling receptors; class 703/subclass 11. Election of database species: Appendix 3.

REMARKS

Applicants submit that restriction between Groups I to VI is unnecessary. According to MPEP § 803, the Examiner should examine all claims in an application, even though they are directed to distinct inventions, unless to do so would create a <u>serious burden</u>. Here, the burden is minimal because of the considerable commonality of elements between the Groups. All the Groups can be searched in the same class 703 and subclass 11. It is not reasonable to consider such a search unreasonable. Moreover, the claims within the Groups I-

VI completely overlap in the <u>all limitations</u>, but for the Appendix of structural data. Surely it can not be considered a serious burden to search these Groups at once. In addition, Applicants request that all other currently pending claims be considered, particularly those claims not made members of any Group provided in the present Action.

The procedure for handling applications that include generic claims is set forth in 37 CFR § 1.146. This rule provides that "[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable." As stated in MPEP § 809.02(a), "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141." Thus, where generic claims are present, an applicant can be required to elect a species for initial examination, but the whole generic claims are still subject to examination to determine whether such generic claims are allowable.

Incomplete Restriction Grouping

The present Action offers grouping of only 5 claims of the currently pending 22 claims. Applicants request that the Restriction Action be withdrawn for failure to provide Groups for election with an opportunity to elect among all pending claims.

Individual Claims Can Not Be Dismembered Based On 35 USC § 121

If the instant action is treated as a restriction requirement under 35 USC § 121, it would split several single claims among multiple restriction groups. This type of restriction requirement is improper as a matter of law. The courts have long held that the section of the patent statute that authorizes restriction practice, *i.e.*, 35 U.S.C. 121, provides no legal authority to impose a rejection on a single claim, even if the claim presents multiple independently patentable inventions. See, In re Weber, 198 USPQ 328, 331 (CCPA 1978); In re Haas, 179 USPQ 623, 624-625 (In re Haas)

I) (CCPA 1973) and In re Haas 198 USPQ 334-337 (In re Haas II) (CCPA 1978). As stated in In re Weber:

"The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim—no matter how broad, which means no matter how many independently patentable inventions may fall within it." 198 USPQ 328 at 334.

In a case such as the instant case, where claims are generic, a restriction requirement is tantamount to a <u>rejection</u> of the claim. The CCPA made this point very clear in *In re Haas I*:

"We find that the action taken by the examiner did in fact amount to a rejection. . . . Those claims were withdrawn from consideration not only in this application but prospectively in any subsequent application because of their content. In effect there had been a denial of patentability of the claims. Presumably only by dividing the subject matter into separate, and thus different, claims in plural applications could an examination of the patentability of their subject matter be obtained." 179 USPQ at 625.

If the instant restriction requirement is allowed to stand, Applicants will never be accorded "the basic right of the applicant to claim his invention as he chooses." *In re Weber*, 198 USPQ at 331. In *In re Weber*, the CCPA stated that "[a]s a general proposition, an applicant has a right to have *each* claim examined on the merits" (198 USPQ at 331, emphasis in original). The Court went on to state that:

"If . . . a single claim is required to be divided up and presented in different applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification." 198 USPQ at 331.

Even if Applicants were to file 6 or more divisional applications to obtain coverage for the claims in each group (and for those claims not afforded a Group) in the Action, they would not have the opportunity to have their broader claims examined. The claims of the divisional applications would be limited to the particular

species set forth in the respective groups. In effect, the restriction requirement is reading limitations into Applicants' independent claims that are not present in the claims as filed. Claim 66, for example, would never be considered under the current restriction requirement. Only the dependent claims which are set forth in the respective groups would be examined.

If the instant action is treated as a restriction requirement, Applicants reserve the right, Pursuant to 37 C.F.R. § 1.144, to petition for review of the restriction requirement at any time prior to appeal. Applicants also note that because the instant rejection is tantamount to a rejection of the generic claims, the restriction requirement is appealable to the Board of Patent Appeals and Interferences. *In re Haas*.

Special Considerations Regarding Unity of Invention

Because the MPEP seems at first glance to consider restriction practice of Markush style claims with respect to Unity of Invention (MPEP 803.02), a great deal of confusion has, unfortunately, become commonplace in the Office as to appropriate restriction practice when considering questions of unity of invention for Markush style claims. It is instructive to consider how this section arose in the MPEP to understand what the law is and what it is not when performing this analysis.

After the *Weber* decision, noted above, a previous version of 803.02 that purported to fashion a rejection for "misjoinder" of a Markush-style claim was actually cancelled out of the MPEP. That is, for a time, the section corresponding to MPEP 803.02 simply stated: "the subject matter formerly under this subtitle has been cancelled in view of the decisions *In Re Weber et al.* 198 USPQ 328 (CCPA 1978) and *In Re Haas* 198 USPQ 334 (CCPA 1978)." In 1980, the Courts again considered the issue of "misjoinder" in the seminal case of *In Re Harnisch* 206USPQ2d 1059, which considered whether there was a non-statutory basis for a rejection for lack of unity *that was entirely distinct from restriction practice authorized by 35 USC 121*. The Court was plainly concerned that the two issues would be confused, noting that:

It should be clear from what we have said that we adhere to our holdings in *In re Weber*, supra and *In Re Haas* (Haas II), supra. Nothing we have said herein is intended to change or modify them in any way; nor do we think

anything said could be construed to have such an effect. The "unity of invention" concept is not to be confused with the "misjoinder" under 35 USC 121 rejection employed in *In re Weber*. In Weber, we dealt with the use of 35 USC 121, which deals only with restriction requirements, to support the rejection of a single claim. Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an improper Markush group.

The Court's concern that the Patent Office would confuse the issues of divisional practice under 35 USC § 121 and unity of invention practice has proven to be well founded. In reinstating MPEP § 803.02, the organizers of the MPEP addressed *Harnisch* (it is the Court decision that now underlies the section), but awkwardly left the original previously cancelled headings for the section in place, seeming to suggest that the issue is really one of restriction practice. As the Court plainly and expressly made clear (*see above*), it is not.

Indeed, as the *Harnisch* court made as clear as humanly possible, the issue when considering "improper Markush" is not an issue of restriction practice at all. Instead, the as the court bluntly stated above, the possibility that a Markush-style claim may lack of unity of invention, is a "distinct ground" of rejection. It has nothing at all to do with restriction practice. *Id.* As *Harnisch* makes entirely clear, improper Markush is not a basis for imposing a restriction requirement at all.

Even the Board decision that the *Harnisch* case was an appeal from had previously reversed the improper Markush rejection by the Examiner, which had been based upon 35 USC § 121 (*Haas* and *Weber*, discussed above, plainly required this result), and fashioned a *different* "improper Markush" rejection based upon unity of invention, an issue gleaned not from statute, but from consideration of judicial precedents (*Harnisch* at 304-305). The Court acknowledged the possibility of such a "unity of invention" style improper Markush rejection under various court precedent (but *not* under statute and, as specifically noted, not under 35 USC §121), but found that a rejection was proper only where the members of the Markush group were "truly independent and distinct." *Id.* at 306, emphasis in the original. The Court made quite plain that this was a high hurdle and that the Office had not shown a lack of unity in the relevant case, because the subject Markush members at issue were all dyes and

could, accordingly, be classified together in a manner that was <u>not "repugnant to scientific</u> classification." *Id.* at 305.

Accordingly, even if "unity of invention" cannot be found amongst the members of a Markush (the central allegation in the subject Restriction Requirement), 35 USC § 121 still does not provide a basis for restriction as the Office has done in the present case. As the noted above, there is simply no such thing as a rejection for misjoinder and, accordingly, rather than restricting elements of a claim away from themselves, the only option open to the Office when attempting to make a rejection for lack of unity of invention is to attempt to make a rejection for improper Markush. As the Courts have definitively ruled, the Office flatly lacks the statutory authority to fashion such a rejection pursuant to restriction practice. There is no exception to this per se rule. The Courts have repeatedly noted the per se nature of this rule, as noted above. The Courts have never held otherwise.

In summary, it is clear that the Action completely confuses the concepts of restriction practice and improper Markush and, in addition, does not establish the requisites for either. In the case underlying MPEP 803.02, i.e., In Re Harnisch, the Court strongly reiterated that the divisional statute does not provide the basis for a rejection of the claims, even in the context of a Markush-style claim. In Re Harnisch 206USPQ2d 300, see, e.g., headnote 6 and page 305. As clearly articulated by the Harnisch Court, the only procedure available to the Office if unity of invention is lacking is to reject the claim for improper Markush on that basis an event that takes place not under the auspices of divisional practice articulated by 35 USC 121, or, indeed, as the Harnisch Court clearly articulated, any statutory section, but under judicially recognized precedent with respect to "unity of invention." The hurdle in making such a unity rejection is high, i.e., that the members of the Markush group must be "truly independent and distinct" (emphasis in the original) or, as the Court stated another way "repugnant to scientific classification." This cannot be established in the present case. In the subject case, of course, the members of the Markush share unity of invention, in that they are not just disclosed as capable of being used together, but are most advantageously used together and are claimed in precisely this way. All members are intervals that provide an essentially similar tool for modeling ligand structures. Thus, there is no basis in the subject case for making an improper Markush rejection,

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any more than there is a basis for restriction of individual components of a claim away from themselves.

Applicants hereby provisionally elect Appendix 3 species (in claims 66, 76, 78, 80 and 82), with the understanding that if the claims are found to be allowable with respect to the elected species, the Examiner will proceed as directed under 37 CFR 1.146 to examine additional species to determine whether the generic claims are allowable in the present application.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 510-769-3510, prior to issuing a Final Office Action.

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

Respectfully submitted,

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Attachments:

- 1) A transmittal sheet; and,
- 2) A receipt indication postcard.